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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR   | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|------------------------|---------------------|------------------|
| 09/780,675      | 02/12/2001  | Nicholas C. Nicolaides | 01107.00098         | 8276             |

22907 7590 06/25/2003

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WASHINGTON, DC 20001

[REDACTED] EXAMINER

AKHAVAN, RAMIN

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1636     | 18           |

DATE MAILED: 06/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/780,675

Applicant(s)

NICOLAIDES ET AL.

Examiner

Ramin (Ray) Akhavan

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

THE REPLY FILED FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a)  The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
b)  The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.  
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.  A Notice of Appeal was filed on 02 June 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2.  The proposed amendment(s) will not be entered because:
  - (a)  they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b)  they raise the issue of new matter (see Note below);
  - (c)  they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d)  they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3.  Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4.  Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5.  The a) affidavit, b) exhibit, or c) request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6.  The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7.  For purposes of Appeal, the proposed amendment(s) a) will not be entered or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_

Claim(s) objected to: 7, 15, 17, 26 and 27.

Claim(s) rejected: 1-6, 8-14, 16, 18-25, 28-31 and 71.

Claim(s) withdrawn from consideration: 32-70.

8.  The proposed drawing correction filed on \_\_\_\_\_ is a) approved or b) disapproved by the Examiner.

9.  Note the attached Information Disclosure Statement(s)( PTO-1449) Paper No(s). 

10.  Other: \_\_\_\_\_

DAVID GUZO  
PRIMARY EXAMINER

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Continuation of 5:

**ADVISORY ACTION**

1. The request for consideration filed on 6/02/2003 under 37 CFR 1.116 in reply to the Final Action Paper No. 14 mailed on 12/31/2002 has been considered but is not deemed to place the application in condition for allowance because the proposed amendments introduce new issues that would require further consideration and/or search.
2. Because the amendment is not being entered, applicant's arguments relying on such amendment are moot, thus will not be addressed.
3. With regard to rejection of claims 1-6, 8-14, 16, 18-25 and 28-31 under 35 U.S.C. §112, first paragraph, applicant has not introduced any new arguments to overcome the basis for rejections already of record. It is noted that applicant's remarks address independent claims 1 and 18; as well as new claims 72 and 73, which will be addressed below. Applicant is reminded that instant amendment is not entered so that any discussion with regard to claims 1 and 18 will be to the claims as-filed and does not include any reference to "PMS2".

In applicant's Remarks (Paper No. 17, Request for Reconsideration), applicant argues that claims 1 and 18 are directed to making bacteria by introduction of a polynucleotide encoding a form of PMS2. However, as-filed the claim 1 reads "[a] polynucleotide encoding a form of a mismatch repair protein...where said mismatch repair protein exerts a dominant negative effect..." or in claim 18, "[w]herein said polynucleotide exerts a dominant negative effect...". Thus the examiner's basis for rejecting the claims as-filed remain. The

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claims as-filed encompass expression of wild-type heterologous mismatch repair genes in bacteria as well as dominant negative alleles of mismatch repair genes.

The claims encompass an entire genus while the specification does not teach such a broad scope. While the specification teaches methods for identifying dominant negative alleles and assays for dominant negative effect, such disclosure is germane to an enablement rejection, not a written description rejection. The specification remains deficient in describing structure-function relationship encompassed by the broad scope of the claims as-filed.

4. With regard to the addition of claims 72 and 73, the claims introduce new issues requiring additional consideration and/or search; it is noted that applicant's disclosure did include "PMS2L", but none of the claims as-filed include any reference to PMS2L. Both 72 and 73 claim embodiments in the specification not previously claimed. The subject matter recited in claims 72-73 raises new issues requiring further search and/or consideration.

Any inquiry concerning this communication should be directed to Ray Akhavan at (703) 305-4454. The examiner can normally be reached on Monday-Friday from 9:00-5:30. If attempts to reach the examiner by telephone are unsuccessful the examiner's supervisor, Dr. Remy Yucel can be reached at (703) 305-1998. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123.

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